#1 GP 920/3305

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket No. 047711/0100

#40

In re INTERIM PATENT TERM EXTENSION OF U.S. Patent No. 4,373,527

SN 06/034,155

Patentee: Robert E. FISCHELL

Assignee: The Johns Hopkins University

Issue Date: February 15, 1983

PETITION FOR EXTENSION OF TIME

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicant hereby petitions the Assistant Commissioner under 37 C.F.R. §1.136(a) for a one-month extension of time for response in the above-identified application for the period required to make the attached response timely.

The extension fee for response within the second month is $380.00. A check for this amount is enclosed herewith.

The Assistant Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Assistant Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

May 8, 2000
Date

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Patentee: Robert E. FISCHELL

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REQUEST FOR RECONSIDERATION OF NOTICE OF FINAL DETERMINATION OF INELIGIBILITY

Attn: Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
For Patent Policy and Projects
Washington, D.C. 20231

The patentee hereby requests reconsideration of the Notice of Final Determination of Ineligibility dated February 7, 2000, in the above-identified interim patent term extension application. On April 27, 2000, during a telephone conference to discuss this matter, Karin Tyson indicated that the patentee should file the instant request for reconsideration now, even though the FDA has not yet responded to the PTO's letter dated March 27, 2000, in which the PTO requested the FDA's comments on whether an application under section 515 (a PMA) was initially submitted prior to Jan. 28, 2000 for the MiniMed product that is the subject of this interim extension application. Ms. Tyson indicated that, in the event the FDA's response to the

PTO's March 27th letter is in any way unfavorable to this application for interim extension, then the patentee will be permitted to submit comments in response to the FDA's determination.

Regardless of any comments the FDA may have, the PTO's determination of ineligibility in this application should be reversed for a number of reasons. The PTO's denial of an interim extension for the '527 patent is based on the fact that, although a PMA was initially submitted before expiration, it was withdrawn before expiration of the patent. As shown below, however, a new PMA shell was submitted prior to expiration of the '527 patent. Moreover, the originally submitted chronology in the interim extension application demonstrates that MiniMed continued to work with the FDA to improve the next PMA submission even after the initially submitted PMA had been withdrawn, thereby demonstrating that review had advanced to the approval stage. Independently of these arguments, the statute does not require anything more than an initially submitted PMA.

A second PMA shell was submitted to the FDA before expiration of the '527 patent. A new PMA shell was submitted to the FDA on Feb. 3, 2000, *before the expiration of the '527 patent*, further demonstrating that the period described in (3)(B)(ii) had begun. *Approval for submitting the shell was received on March 28, 2000.* The first module of the new shell was submitted to the FDA on March 31, 2000. The second module was submitted to the FDA on April 5, 2000. The third module was submitted to the FDA on April 27, 2000. The complete PMA is anticipated to be filed in early June of 2000. Therefore, the applicant had clearly advanced to the approval period prior to expiration of the '527 patent, even though the intiially submitted PMA was withdrawn.

The timeline in the originally submitted interim extension application also evidences activity relating to the approval phase even after withdrawal of the initially submitted PMA. The timeline provided in the originally submitted interim extension application contains the following entries demonstrating that the period described in (3)(B)(ii) had continued (despite withdrawal of the initially submitted PMA):

Date	Description
10/26/99	fax to Pat Cricenti of FDA regarding MiniMed's intention to submit PMA application for the MIP system
11/19/99	fax to Mary Joe Robinson of FDA with proposed agenda for meeting to discuss MIP systems PMA application
12/7/99	meeting between MiniMed representatives and FDA regarding MIP system PMA application
12/23/99	letter to Pat Cricenti of FDA regarding results of 12/7/99 meeting to discuss MIP system

The record shows that the FDA and MiniMed were continuing to engage in activities and dialog related to PMA re-submission, which represents a continuation of the period described in (3)(B)(ii).

The statute only requires an "initially submitted" PMA, not a pending PMA. The statute nowhere requires that an initially submitted PMA must be still be pending on the date of expiration (or on the date of filing the interim extension application). All that the statute requires is for the period "described in ... [35 U.S.C. 156(g)](3)(B)(ii)" to have begun. The period described in (3)(B)(ii) begins on the "date an application was ***initially submitted*** with respect to the device under section 515" (emphasis supplied). Thus, the statute expressly contemplates a situation where a PMA may be withdrawn and re-submitted (not necessarily before the filing of an interim extension application). The bottom line is that the period described in (3)(B)(ii) had begun before the instant interim extension application was filed. The initially submitted PMA was complete enough to have been assigned a PMA number, as detailed in the originally submitted interim extension application.

Requiring a pending PMA could cause FDA applicants to work against the FDA. Yet another reason compelling reversal here is that the PTO's interpretation of section 156 could lead to a policy causing applicants to work against the FDA by disregarding FDA requests to voluntarily withdraw a PMA. Under the PTO's interpretation, an FDA applicant would be better off in terms of being eligible for an interim extension by keeping the PMA on file and forcing the

FDA to reject it. In the instant case, MiniMed voluntarily withdrew the initially submitted PMA at the FDA's request to obtain additional information. Thus, not only is the requirement to have a pending PMA on file at the time of filing an interim extension application contrary to the statute, it is also bad policy.

In accordance with the foregoing remarks, favorable reconsideration and an indication of eligibility for interim extension are requested.

Respectfully submitted,

May 8, 2000
Date

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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.